UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	)	
	)	**Docket No. 05-16**
LYLE CRAKER, PH.D.	)	

GOVERNMENT'S MOTION IN LIMINE TO EXCLUDE RESPONDENT'S PROPOSED TESTIMONY AND LISTED EXHIBITS PURSUANT TO 5 U.S.C. § 556(d) and 21 C.F.R. § 1316.59(a)

The Government, by and through the undersigned attorney, requests the Administrative Law Judge (ALJ) to issue an order, which will exclude the testimony of four of Respondent's proposed witnesses and some of Respondent's proposed documents that are listed in the "Respondent's Pre-hearing Statement [Initial]" based upon 5 U.S.C. § 556(d) and 21 C.F.R. § 1316.59(a).[1] The Government's grounds for requesting this order are set forth more fully below.

Applicable law- 5 U.S.C. § 556(d) and 21 C.F.R. § 1316.59(a)

Title 5 U.S.C. § 556(d) requires the agency, as a matter of policy, to exclude evidence that is "irrelevant, immaterial, or unduly repetitious." This statute is not discretionary because it states "the agency ... **shall** provide for the exclusion ..." of such evidence. (Emphasis supplied.)

[1] The Government intended originally to move to exclude most of the articles set forth in the Respondent's initial prehearing statement, but when Respondent provided copies of its documents to the Government, Respondent did not provide most of the articles listed in its initial prehearing statement. Thus, the Government assumes that the articles not provided to the Government will not be proffered by Respondent.

Likewise, 21 C.F.R. § 1316.59(a) requires the ALJ to admit "**only** evidence that is competent, relevant, material and not unduly repetitious." (Emphasis supplied.) Both Rule 1316.59(a) and Section 556(d) use the word "shall," a clear indication that this rule is not discretionary. Thus, under Section 556(d) and Rule 1316.59(a), DEA is required to exclude evidence that is incompetent, irrelevant, immaterial, or unduly repetitious.

Reviewing courts have consistently upheld agencies' decisions to exclude irrelevant, immaterial, or unduly repetitious evidence during on-the-record administrative adjudications. *Siegel v. Atomic Energy Commission*, 400 F. 2d 778, 784 (D.C. Cir. 1968) (Commission could restrict the hearing to exclude evidence pertaining to the factor of foreign enemy attack because the statute on which the hearing was based did not consider such factors). *Alabama Assoc. of Insurance Agents v. Board of Governors of the Federal Reserve System*, 553 F.2d 224, 253-254 (5th Cir. 1976)(upholding the agency's exclusion of parts of an expert's testimony because such testimony was cumulative and irrelevant to the issues in the proceeding); *Fried v. United States*, 212 F. Supp. 886, 896 (S.D.N.Y. 1962) (affirming the agency's exclusion of evidence that was cumulative or immaterial to the issues presented and explaining that "... the Administrative Procedure Act clearly sanctions the exclusion of evidence which is irrelevant or cumulative."); *Carstens v. NRC*, 742 F.2d 1546, 1553-1554 (D.C. Cir. 1984) (affirming NRC's exclusion of expert's testimony based upon incompetence of his expertise and irrelevancy).

Summary of the Government's Argument

The ultimate legal issue in this matter, as framed by the ALJ in her Prehearing Ruling is "[w]hether a preponderance of the evidence establishes that granting

Respondent's application ... as a manufacturer of the Schedule I controlled substance marijuana would be in the public interest as that term is used in 21 USC § 823(a)." (Prehearing Ruling, pg. 1, ¶ 1) The primary factual issue, however, as framed by Respondent, is whether the current cultivator of research marijuana, the University of Mississippi, produces an adequate quantity or acceptable quality of marijuana for research purposes, and whether another cultivator of marijuana is needed to supply marijuana for scientific investigations and new drug products.

Much of Respondent's proposed testimony and documentary evidence, however, are not at all relevant to any of the factors at 21 U.S.C. §§ 823(a)(1) through (6) that must be used to determine whether Respondent's manufacturing application is in the public interest. Even if the Government were to assume, *arguendo,* that Respondent's proposed testimony and documentary evidence are true and valid, they would have no relevance to and no effect on any of the six factors enumerated in § 823(a). Moreover, much of Respondent's proposed testimony and documents are unduly repetitious.

Under 21 U.S.C. § 823(a)(1), DEA must register a manufacturer of Schedule I controlled substances only if the current manufacturer cannot "... produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes." The articles and witnesses listed in the Respondent's initial prehearing statement and listed below do not address this issue. In other words, even if one assumed that everything about that these witnesses and articles is true, it would not have any impact on the issue of whether the current supplier of marijuana, the University of Mississippi, would be able to "...

produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes."[2] The reason why this issue is a threshold issue and why the testimony and documents noted herein must be excluded is that if the University of Mississippi is able to "... produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes[,]" then the registration of the University of Massachusetts would be superfluous and only a contingency registration at best. DEA does not as a matter of policy grant contingent or "shelf" registrations.

The following articles set forth in the documents submitted by Respondent should be excluded:

Martin, William J. (1999). Basic Mechanisms of Cannabinoid-Induced Analgesia. This article discusses various studies as to the effects of cannabis on pain. The article concludes that cannabis might have a beneficial effect on pain if undesirable side effects can be eliminated. (R-16)[3]

Doblin, R.E., and Kleiman, M.A.R. (1991). Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes. Journal of Clinical Oncology 9(7):1314-1319. This is an article detailing the results of a 1990 survey of randomly selected members of the American Society of Clinical Oncology. The survey solicited opinions regarding the use of marijuana as a treatment for emesis (vomiting) in cancer patients. The survey was designed to determine whether a significant minority of members supported the rescheduling of marijuana to permits its use in the treatment of nausea associated with cancer chemotherapy. The authors concluded that marijuana has a "currently accepted medical use" because it was generally accepted by a "respectable minority of physicians," and therefore rescheduling was appropriate. (R-22)

Vinciguerra, V., Moore, T., Brennan, E. (1988). Inhalation Marijuana as an Antiemetic for Cancer Chemotherapy. New York State Journal of Medicine. 88:525-527. This article details a 1988 study of the use of inhaled marijuana as an antiemetic

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[2] The Government reserves the right to make this objection at the hearing for other witnesses or documents that contain the same type of evidence for those witnesses or documents that set forth both relevant and irrelevant material. For purposes of this motion, however, the Government seeks to exclude the entire witness or document listed.

[3] "R- " refers to Respondent exhibit numbers listed in its documents.

agent for cancer chemotherapy patients. The 56 patients self-reported their subjective opinions of the overall effectiveness of the marijuana. The study was inconclusive, and admitted that other studies that quantitate emetic episodes would provide objective and precise information. (R-20)

Russo, E. Mathre, M.L., Bryne, A., Velin, R., Bach, P.J., Sanchez-Ramos, J., and Kirlin, K.A. (2002). Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Affects of Legal Clinical Cannabis. J. Cannabis Ther 2(1):3-58. This article describes a study of the therapeutic benefits and adverse effects of prolonged use of smoked marijuana by seriously ill patients. It describes the case histories and clinical examination of four patients that were receiving marijuana cigarettes from the National Institute on Drug Abuse (NIDA) for a variety of medical conditions. Use of the marijuana was approved through the Compassionate Investigational New Drug (IND) program of the Food and Drug Administration. Patients were being treated for glaucoma, multiple sclerosis, and pain and muscle spasm associated with nail-patella syndrome, and multiple congenital cartilaginous exostoses. Duration of use of marijuana in this program ranged from 10 years to 19 years. Prior to enrollment to this program, the patients reported self-medicating with marijuana for 1 year to 19 years. Russo and colleagues concluded that: (1) "Cannabis smoking, even of crude, low-grade product, provides effective symptomatic relief of pain, muscle spasms, and intraocular pressure elevations in selected patients failing other modes of treatment;" (2) "The side effect profile of NIDA cannabis in chronic usage suggests some mild pulmonary risk;" (3) "No consistent or attributable neuropsychological or neurological deterioration has been observed;" (4) "No endocrine, hematological or immunological sequelae have been observed." The article discusses some problems in the Compassionate IND Program, including an inadequate supply or provision of inferior quality cannabis. (see pages 47-51).[4] (R-19)

De Jong, B.C., Prentiss, D., McFarland, W., Machekano, R., and Israelski, D.M. (2005). Marijuana Use and Its Association with Adherence to Antiviral Therapy Among HIV-infected Persons with Moderate to Severe Nausea. J. Acquired Immune Deficiency Syndrome 38(1):43-46. This article studies how marijuana use affects adherence to prescription medicine therapy in patients with HIV and nausea. The role of marijuana in facilitating adherence to therapy was conflicting. Two studies showed a negative correlation between marijuana and adherence to therapy, while some patients reported that smoking marijuana improved their adherence to therapy. Thus, the authors sought to identify which subgroup of HIV-infected patients adhered to therapy in association with recent marijuana use. The study concludes that more conclusive assessments of the effect of marijuana on adherence require more study. (R-17)

Abrams, D. I., Hilton, J. F., Leiser, R.J., Shade, S.B., Elbeik, T.A., Aweeka, F.T., Benowitz, N.L., et al. (2003). Short-Term Effects of Cannabinoids in Patients with HIV-1 Infection. Ann Intern Med 139:258-266. This article examined the short-term effects of smoked marijuana and dronabinol (capsulated, synthetic THC) in 62 HIV

[4] To the extent this article makes the claim that the marijuana currently provided for research is of insufficient quality and quantity, the Government would not object to the relevancy of this article.

patients. Patients were randomly administered either smoked marijuana, dronabinol group, or a placebo. The study concluded that oral and smoked marijuana did not have harmful effects on HIV patients' immune system, however, these results needed to be confirmed in larger and longer trials. (R- 18)

The above-listed articles concern past scientific research devoted exclusively to the potential virtues and risks of using marijuana as medicine. The medical efficacy of marijuana is not an issue in this proceeding, however. Respondent has not applied to conduct research under 21 U.S.C. § 823(a), nor has Respondent petitioned to reschedule marijuana.

Respondent has filed an application to manufacture marijuana, and the articles are not relevant to the issue of whether Dr. Craker's application to manufacture marijuana should be granted, in consideration of the primary issue of marijuana quantity and quality and the factors to be considered listed at 21 § U.S.C. 823(a). The only factor at § 823(a) that has any relation to research is § 823(a)(3): "promotion of technical advances in the art of manufacturing these substances and the development of new substances." Thus, the question raised by this factor would be whether the medical marijuana available now is sufficient to comply with the requirements of § 823(a)(3).

The articles have no relevance to the question of whether granting Respondent a DEA registration would lead to advances in manufacturing of marijuana or whether marijuana grown by Respondent would lead to new "substances." Past research into the effects of marijuana on animals and humans has no relevance to the success of Respondent's future endeavors. Moreover, none of the past research in the articles submitted by Respondent appears to have

any similarity to Respondent's planned research as described in Respondent's prehearing statement.

It is undisputed that marijuana research is ongoing; both parties intend to proffer testimony to this effect, and the Government will agree to stipulate to this fact. The plethora of articles concerning past research submitted by Respondent, however, are irrelevant to the facts at issue in this matter and unduly repetitious. None of these articles addresses the crucial issue whether the current supplier of marijuana, the University of Mississippi, would be able to "... produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes."

The following testimony listed in Respondent's prehearing statement should be excluded:

Proposed testimony of Angel Raich: Ms. Raich's proposed testimony is limited to her experience as a patient who uses marijuana and her belief that marijuana research should increase. Ms. Raich "will also testify that she has a federal court injunction precluding the federal government from prosecuting her for her medical use of marijuana."

Proposed testimony of Valerie Corral. Ms. Corral's proposed testimony is similar to Ms. Raich's. In addition, her proposed testimony includes the assertion that she is a founder of the Wo/Men's Alliance for Medical Marijuana (WAMM), a group that advocates that marijuana should be considered medicine for certain illnesses.

Ms. Corral also will testify that DEA "raided" a WAMM "garden" and confiscated the "medicine." This proposed testimony notes that the federal government was enjoined from seizing the marijuana by an injunction, which permitted the WAMM "garden" to operate pending the resolution of *Gonzales v. Raich.*

The proposed testimony of Ms. Raich contains anecdotal evidence of the benefits of the use of marijuana as medicine. Ms. Corral's proposed testimony contains pleas for further research into such use. The proposed testimony of both witnesses discusses injunctions imposed against the government.

This kind of testimony is not relevant to the issue of whether DEA should grant Respondent's application for manufacturing marijuana in light of Respondent's assertion he needs more and better quality marijuana for the research of others. Personal opinions and anecdotal evidence that marijuana is useful as medicine and should be studied further are not relevant in this regard. Respondent may argue that future research would make a pharmaceutical concern more interested in developing a marijuana product, and, therefore, testimony about the need for more research is necessary. However, such evidence would have no relevance because future research is highly speculative. Respondent, in the testimony noted herein, provides no evidence of actual, desired research that is precluded by the alleged lack of quantity or quality of marijuana.

Again, such testimony, even if accepted at face value, would not have any impact on the issue of whether the current supplier of marijuana, the University of Mississippi, would be able to "... produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes."

Moreover, any "impediment" to research would be the result of HHS, not DEA, policy.

The proposed testimony concerning the injunctions is also irrelevant, because such testimony is now moot in light of the very recent Supreme Court decision in *Gonzales v. Raich*, ___ U.S. ___, 125 S. Ct. 2,195 (2005).

Proposed Testimony of Irwin G. Martin, Ph. D.- Respondent notes in his prehearing statement that Dr. Martin is an expert in the field of drug development. Dr. Irwin will testify about the need for standardized drug features, the FDA drug approval process and the need for a pharmaceutical to have a ready source and supply of the drug needed during the developmental stages. As such, according to Dr. Martin's proposed testimony, a ready source of the drug should be manufactured for the drug development process.

Again, even if one assumes that this testimony is true, its does not address the ultimate issue of whether the current supplier of marijuana, the University of Mississippi, would be able to "... produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical scientific research and industrial purposes."

The following testimony and book listed in Respondent's prehearing statement should be excluded:

Proposed Testimony of Lester Grinspoon, M.D., and Grinspoon, M.D., Lester, and Bakalar, James B., Marijuana, the Forbidden Medicine, New Haven, Ct.: Yale University Press (1993).

Dr. Grinspoon's proposed testimony, to which the Government seeks to exclude from the hearing is set forth in Respondent's prehearing statement as follows: "He will testify that he has been studying cannabis since 1967 and have [*sic*] published two books on the subject. In 1971 Marihuana Reconsidered was published by Harvard University Press. Marihuana , the Forbidden Medicine, coauthored with James B. Bakalar, was published in 1993 by Yale University Press; the revised and expanded edition appeared in 1997. Dr. Grinspoon will testify generally about the history of cannabis as medicine; whether there is 'accepted medical use' of cannabis; ..."

Dr. Grinspoon's testimony, as noted from the summary of his testimony and the preface to his 1993 publication, *Marihuana , the Forbidden Medicine*, relates to anecdotal stories concerning the effects of "medical" marijuana on various ailments as noted in the preface, i.e., patients' personal stories on how they believed marijuana affected their various medical conditions. (R- 21, pg. xii) Indeed, the preface acknowledges that some of these anecdotes come from the 1986 DEA administrative hearing in which the petitioners sought, unsuccessfully, to reschedule marijuana based, in part, on the rationale that anecdotal evidence was a policy judgment that did not compel the agency to reschedule marijuana. *Alliance for Cannabis Therapeutics v. DEA*, 930 F. 2d. 936 (D.C. Cir. 1991), *affirmed after remand*, 15 F. 3d 1131 (D.C. Cir. 1994). Since this type of testimony has been rejected for purposes of rescheduling marijuana, it should, *a fortiori*, be rejected as evidence to determine whether an application to manufacture marijuana should be granted or not.

Conclusion

Based upon the foregoing, the Government respectfully requests that the Administrative Law Judge grant the Government's motion to exclude the documents and testimony proffered by Respondent described above, based upon irrelevancy and repetitiveness.

Respectfully submitted,

FOR

Brian Bayly
Attorney, Office of Chief Counsel

Dated: July 22, 2005

CERTIFICATE OF SERVICE

On July 22, 2005, I sent a copy of the foregoing by facsimile, (202) 661-4810, to Counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 Thirteenth Street, NW, Washington, D.C. 2005, and had two copies with the original delivered to the DEA Office of the Administrative Law Judges.

Paulette Morgan